

**Economic Impact Statement**  
LSA Document #22-119

**IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses****Description of the Rule**

This rule amends [410 IAC 29](#) to update definitions and to lower the standard for an elevated blood lead level. Lowering the standard underscores lead's danger as a neurotoxin and provides services to families of children from lead exposure.

**Economic Impact on Small Businesses****1. Estimate of the number of small businesses, classified by industry sector, that will be subject to the proposed rule.**

[IC 5-28-2-6](#) defines a small business as a business entity that satisfies the following requirements:

- (1) On at least fifty percent (50%) of the working days of the business entity occurring during the preceding calendar year, the business entity employed not more than one hundred fifty (150) employees.
- (2) The majority of the employees of the business entity work in Indiana.

This rule should not have any significant impact on small businesses because it primarily affects governmental entities. However, some health care providers that qualify as small businesses may find that they need to provide additional lead testing and clinical direction to families of children now identified as having an elevated blood lead level. Those affected providers are going to be most commonly family physicians and pediatricians.

**2. Estimate of the average annual reporting, record keeping, and other administrative costs that small businesses will incur to comply with the proposed rule.**

This rule does not change reporting requirements for providers as they are already required to report all blood lead testing to IDOH. Costs for record keeping will be negligible as lead test results are already a common field in providers' electronic medical record keeping systems.

**3. Estimate of the total annual economic impact that compliance with the proposed rule will have on all small businesses subject to the rule.**

Providers may be required to perform additional tests on patients. All lead testing is a covered expense for patients on Medicaid, and per a survey of providers from the Indiana Department of Insurance, insurers identify lead as a covered service under health insurance policies.

Meridian Bioscience, the manufacturer of the only point-of-care lead testing device on the market, identified the average national reimbursement at \$13 under private insurance and \$17.11 for Medicaid in Indiana. Assuming an additional 1,283 children are identified as elevated under the new definition, each of those children will require 2 to 4 follow-up tests per year, and if 40% of the children are covered by Medicaid, the total reimbursement to providers would total \$34,792 (\$18,538 under private insurance and \$16,254 under Medicaid).

**4. Statement justifying any requirement or cost that is imposed on small businesses by the rule; and not expressly required by the statute authorizing the agency to adopt the rule; or any other state or federal law.**

Any additional requirement or cost that may affect small businesses is justified because this rule change will help identify children with elevated blood levels to help prevent future lead exposure.

**5. Regulatory Flexibility Analysis**

Other factors considered:

**A. Establishment of less stringent compliance or reporting requirements for small businesses.**

There is no safe level of lead in blood. Less stringent compliance or reporting requirements could risk additional lead exposure for children who have an elevated blood lead level.

**B. Establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.**

Less stringent schedules or compliance deadlines would risk additional, undiagnosed lead exposure for children who have an elevated blood lead level.

**C. Consolidation or simplification of compliance or reporting requirements for small businesses.**

The compliance and reporting requirements for health care providers are as simplified as they can be to protect the health of children. Current, effective processes will remain in place and IDOH staff will work with providers to connect their electronic reporting systems to the state's to maximize automated reporting.

**D. Establishment of performance standards for small businesses instead of design or operational standards imposed on other regulated entities by the rule.**

Performance standards will not accomplish the goals of this rule change.

**E. Exemption of small businesses from part or all of the requirements or costs imposed by the rule.**

The requirements of this rule are needed from all health care providers so that providers who qualify as small businesses cannot be exempted.

**Conclusion**

Costs to healthcare providers in complying with the new rule will be covered by Medicaid and private insurance. The more significant costs for implementing this rule will fall to local health departments and IDOH, and those costs are slated to be covered using discretionary funding from HB 1007.

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